REMARKS

In the Office Action mailed October 9, 2007 from the United States Patent and Trademark Office, the Examiner rejected claims 1, 3-10, 12 and 13 under 35 U.S.C. 112, first paragraph; claims 1, 3-8 and 9, 10, 12 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Gidlund U.S. Patent No. 6,436,449 ("Gidlund"). Accordingly, Applicant respectfully submits the following.

Rejections Under 35 U.S.C. §112

In the pending Action, claims 1, 3-10, 12 and 13 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. In particular, the Action indicated that claim1 further stipulates that *Morinda citrifolia* is given twice per day. This limitation has been removed from claim 1. The Action indicates that claim 9 stipulates that each dose of juice is an amount between 2 and 3 ounces. This limitation has been removed from the claim. The Action further indicates that the term "about" in the independent claims is not supported in the application as originally filed. The term "about" has been removed as a limitation from the independent claims. Finally, the Action indicates that the instant specification does not indicate that the concentration is expressed as a volumetric percentage rather than another expression of concentration, such as mass percentage. However, within the context of the experiment, volumetric percentage is inherently disclosed. In particular, Example 1 consistently expresses the amount of constituents utilized by volume. Accordingly, Applicant requests that all §112 rejections be withdrawn at this time.

Rejections Under 35 U.S.C. §103

Applicant respectfully submits that Gidlund fails to teach the administration of a dilute *Morinda citrifolia* product to produce selective COX-2 inhibition. The results produced by administering the dilute *Morinda citrifolia* product as claimed were unexpected.

Applicant's claims contain limitations which require that the juice be administered in a very specific amount by volume in order to limit undesired COX-1 inhibition. Applicants' disclosure demonstrates unexpected results when administering the appropriate concentration of *Morinda citrifolia.* In particular, Applicant's experiments provide the unexpected discovery that at some concentrations, selective COX-2 inhibition was achieved, and at other concentrations it was not. The specification indicates, "[t]he data suggests the surprising result that in some circumstances 'less' *Morinda citrifolia* juice provides 'more' inhibition selectivity." Specification, pg. 15. Applicant's disclosure shows that COX-2 selectivity is undermined by excessive, increased concentrations. Specification, pg. 15. It is only after the inherent COX-1 inhibiting qualities of *Morinda citrifolia* are limited by the methods of the present invention that selective COX-2 inhibition occurs. Modifying the concentration of *Morinda citrifolia* juice reduces the selective COX-2 inhibition properties of the administration.

In addition to the unexpected results detailed in the specification, attached please find research data supplied by the inventors, which supports the claims that a composition of *Morinda citrifolia* is an effective selective COX-2 inhibitor. Specifically, the present composition of *Morinda citrifolia* acted as a selective COX-2 inhibitor providing relief from inflammation associated with COX-2.

The noninvasive administration of a composition to eliminate the unwanted side effects of traditional non-steroidal anti-inflammatories is a long felt need in the industry, and is

addressed by the present invention. Compounds or formulations, which favorably influencing pain, do not have a reasonable probability for reducing pain by selective COX-2 inhibition. For example, a popular treatment of chronic pain and inflammation involves the use of non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs inhibit both COX-2 and COX-1.While NSAIDs have been effective in reducing inflammation and pain, NSAIDs have a number of adverse side effects. The major side effects of NSAIDs are gastrointestinal related. In order to provide relief pain associated with COX-2 without inhibiting COX-1, drug companies have attempted to produce selective COX-2 inhibitors (e.g., VIOXX), with limited success and with potentially dangerous side effects. Accordingly, the claimed product satisfies a long felt industry need by providing an effective selective COX-2 inhibition, which does not produce any unwanted side effects.

Gidlund teaches the administration of a full strength extract from juice; while the present invention claims the administration of a dilute product. Gidlund teaches use of an extract derived from the fruits, leaves, the bark or the roots of *Morinda citrifolia* for the manufacture of a medicament for the treatment of a mammal suffering from tinnitus. In particular, Gidlund fails to disclose administration of an appropriate concentration of extract to achieve selective COX-2 inhibition. Gidlund discloses that the "liquid extract from *Morinda citrifolia* will be present in an amount such as to provide a daily dosage of 0.1-2 ml, or 0.2-1 ml . . . per kg body weight of the patient" (See col. 5, ln. 15-19), with no reference to, or limitation on a concentration of the *Morinda citrifolia*-derived liquid extract whatsoever (administering between 8 and 106 ml of liquid Morinda citrifolia juice to a 80kg patient daily).

Gidlund's full strength product administered without dilution fails to teach the administration of a M. *citrifolia* product to produce selective COX-2 inhibition. The specification

describes the use of processed *M. citrifolia* to treat pain and inflamation and details the unexpected benefit of providing selective COX-2 inhibition. As described in example 1 of the specification of the present application, the dosaging of *citrifolia* juice is critical to achieving selective COX-2 inhibition. If an excessive amount of juice is administered, the selective COX-2 properties of the *citrifolia* juice are diminished.

Because the cited prior art fails to teach or suggest all claim limitations of the present invention, and because the claimed product produces unexpected benefits that satisfy a long felt industry need, Applicants submit that the present invention is not obvious. Accordingly, Applicant respectfully requests that the §103 rejections be withdrawn at this time.

CONCLUSION

Applicants submit that the claims are now in condition for allowance. Accordingly, Applicants request favorable reconsideration. If the Examiner has any questions or concerns regarding this communication, the Examiner is invited to call the undersigned.

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